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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,726	04/12/2001	Richard A. Gambale	B0410/7278	7561
22832	7590	01/25/2006	EXAMINER	
KIRKPATRICK & LOCKHART NICHOLSON GRAHAM LLP (FORMERLY KIRKPATRICK & LOCKHART LLP) 75 STATE STREET BOSTON, MA 02109-1808			MENDEZ, MANUEL A	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/743,726	Applicant(s) GAMBALE ET AL.	
	Examiner Manuel Mendez	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07/06/2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5-11 is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>October 24, 2005</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Group I: Claims 1-4

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hayman in view of Leone, et al. or Fagan, et al., and in further view of Peiler, et al., and Billeter, et al., and in further view of Kallok**. The Hayman patent discloses an agent delivery system having a pellet containing therapeutic agent, a flexible, implantable body having a hollow interior configured to received and retain the pellet within the interior after the body have been implanted within tissue. Hayman does not disclose a helical spring having individual coils which define an inside diameter suitable for retaining a pellet in position within the device and the coils being spaced a distance which permits bodily fluids to flow into the interior of the device and yet small enough to prevent passage of the pellet from the interior of the device. However, the structural and functional enhancements described above are conventional in view of the teachings of Leone, et al., Fagan, et al., and in further view of Kallok.

The infusion of pellets into the body using a stent (coils) can be performed within the tubular space of each one of the coils as shown by Leone, et al. or by

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retaining the drug within the axial tubular space created by the stent as disclosed in Fagan, et al. Moreover, the infusion of medicaments into tubular structures located within the body is a well-known concept as shown by Peiler, et al. As long as the medical device has a wall capable of retaining a drug or medicament, such drug or medicament can be deployed into the tubular body in order to be retained in the tubular structure.

The Kallok patent has been added to this rejection to demonstrate that it is conventional in the art for agent delivery systems to have openings that permit the flow of body fluids into the system in order to make contact with a pellet.

Based on the observations above, a person of ordinary skill in the art would recognize that a design containing numerous helical coils would create a wall capable of retaining a drug within its interior. Therefore, the infusion of drugs or medicaments into tubular structures located within the body would have been considered an obvious design choice.

Finally, concerning **claims 3 and 4**, Billeter, et al., teaches the importance of tubular diameters in order to retain infused medicaments. In figures 1 and 3, pellets (2) are retained in the tubular structure because their diameter is greater than the diameter of the tubular medical device. Based on the teachings of Billeter, et al., a person of ordinary skill in the art would have recognized that in order to restrict the movement of pellets within a tubular medical device, the tubular structure of the holder must have a smaller diameter than the pellets. Accordingly, for a person of ordinary skill in the art, altering the diameter of the

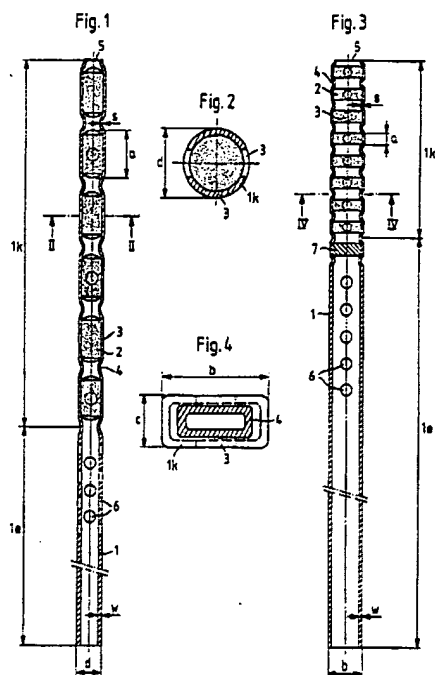
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tubular medical device (holder) in order to restrict the movement of pellets would have been considered an obvious design choice.

Response to Arguments concerning Claims 1-4

Claim 1 has been amended with the phrases (1) implantable in tissue, (2) a coil, and (3) [to permit bodily fluid to enter the interior and] come in contact with the pellet.

In relation to the phrase "implantable in tissue", it is noted for the record that a recitation with respect to the manner in which an apparatus is intended to be employed does not impose any structural limitation upon the claimed apparatus, which differentiates it from a prior art reference disclosing the structural limitation of the claim. In re Pearson, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974). Accordingly, the phrase in question does not provide the necessary patentable weight to overcome the pending rejection.



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Billeter, et al.

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In relation to the term "coil", Leone, et al., shows various configurations of coils, and finally, in relation to the opening to permit bodily fluid to come in contact with the pellets, Billeter, et al., shows in figures 1-3, openings in the apparatus to permit the flow of fluid to come into contact with the medicine carriers or pellets.

Group II: Claims 5-11

Claims 5-8 and 9-11 are allowable over the prior art of record. The following is a statement of reasons for the indication of allowable subject matter: In relation to independent claims 5, 9 and 11, the prior art of record does not disclose or suggest the use of a pellet delivery tube and an implant delivery device to infuse pellets into the apparatus **after the body has been implanted within tissue.**

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will

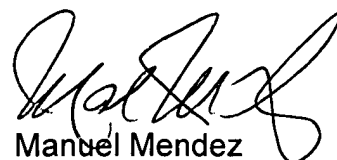
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the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel Mendez whose telephone number is 703-272-4977. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Manuel Mendez
Primary Examiner
Art Unit 3763

MM